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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,658

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Roberto Giardino

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EXAMINER

COLQUITT, AARON BRUCE

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,658	<b>Applicant(s)</b> GIARDINO ET AL.	
	<b>Examiner</b> AARON B. COLQUITT	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/09/2006</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Specification***

1. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Pub. No.: US 2003/0093028 A1 to Spiegel (hereinafter “Spiegel”).

#### **In Reference To Claims 1 and 12-14**

Spiegel teaches an apparatus and method for an electromagnetic field stimulator for use on the human body [0045-0049], in which means [0063] of current generation (19, 20) are suitable for powering at least one solenoid (17, 16) to generate an electromagnetic field (18), characterized in

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that the means for current generation supplies said solenoid (17, 16) with current ( $I(t)$ ) having a waveform (23) that includes the repetition of a linear ramp (fig. 7) with a certain slope [0075].

Spiegel teaches:

[0045] The present invention creates an induced DC-like electric field in biological material to treat the material. The biological material can be portions of a living human or animal, such as body fluids, cells, tissue, or bone.

[0046] The induced DC-like electric field can treat the biological material in numerous ways, including promoting regeneration of damaged tissue. For example, the DC-like electric field can treat trauma (e.g., bruises, torn muscles, and cartilage damage); debilitation; organs by stimulating their regeneration to restore their functions; damaged or severed human nerves or axons; slow or non healing bone fractures (nonunions); occlusion of blood flow due to formation of plaque or other forms of calcification in the blood stream; ailments such as heart disease and senility, resulting from reduced blood flow to the affected organ; or osteoporosis (both prevention and reversal).

[0047] The induced DC-like electric field also can treat the biological material by destroying it or disrupting its normal processes. For example, cancerous tissues within the human body can be treated by inducing high electric currents.

[0048] The induced DC-like electric field also can be used to increase migration of electrically charged materials through the biological material. For example, the induced DC-like electric field can enhance transdermal transport of efficacious ionic drug components to specific locations within the tissue, thus reducing the amount of drug needed as well as toxic effects from the drug.

[0049] The induced DC-like electric field also can decrease human nerve pain by blocking electrical signals along nerve paths.

Spiegel teaches the apparatus induces a DC-like electric field in the biological material by subjecting it to a stepwise time changing magnetic field. The ions exposed to a time changing magnetic field are subject to a force that will produce electric currents that will oppose the change in the magnetic field [0050]. Stepwise changing magnetic fields of up to 2000 gauss can be achieved by both permanent and electromagnets and the system can generate electric field strength in the biological material in the range of

0.000V/m to 100.0 V/m (volts per meter). The system can also generate an electric current in the biological material in the range of 0.000001 amperes to 10.0 amperes [0076].

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spiegel in view of EP 1138348 A2 to Bierbaumer (hereinafter “Bierbaumer”).

**In Reference To Claims 2-11 and 15**

Spiegel teaches an electromagnetic field stimulator in which at least one solenoid is used to generate an electromagnetic field onto the body comprising a current having a waveform that includes a repetition of a linear ramp but fails to teach a table in which at least one function is stored that provides an output value that expresses a target current intensity.

Bierbaumer teaches a magnetic field generator in an apparatus, such as a compact unit from a mat. The mat (3) is flexible and can be used to aid in the treatment of human and animal [0077] tissue that comprises coils (23) which are arranged within the fabric [0078]. The impulses from the generator are variable and selectable by the user by having a selection of programs of impulse samples stored into the magnetic field generator by way of factory-installed samples or via the internet by the integration of a PC and software programs. The magnetic field generator (2) connects to an energy source (17) and a control device (4) generates a pulsed current and has

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a digital part with a micro-controller (7) that has memory storage (8) for permanent storage and for reading off impulse patterns as required. A temperature regulator (26) on the mat allows for the manual or automatic selection and adjustment of the temperature of choice and regulation via the control equipment (4) of the magnetic field generator [0086], wherein the heat of the heater circle (25) can amount up to 50 Watts, which is preferably supplied by the control equipment (4) of the generator in the form of DC voltage with up to 50V. Fig. 3 displays the graphical impulses of the magnetic field generator. The impulses (29) can be produced in a linear manner like saw teeth waveform.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an electromagnetic field stimulator comprising a solenoid that causes an electromagnetic field similar to that of Spiegel with a micro-controller that has memory storage similar to that of Bierbaumer in order to provide for an electromagnetic field stimulator that has its linear field impulse generated by the signal inputted by the micro-controller that can allow for the maintenance and adjustment of the generated field to aid in the ease of the device for those of different therapeutic needs.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have an electromagnetic field stimulator comprising a solenoid similar to that of Spiegel with a solenoid of sufficient flexibility to be incorporated into a fabric designed to provide warmth to a patient similar to that of Bierbaumer in order to provide for a therapeutic apparatus that can be worn by the user in a variety of settings.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have an electromagnetic field stimulator comprising a solenoid similar to

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that of Spiegel with a regulator and micro-controller similar to that of Bierbaumer in order to provide for an apparatus that can monitor and adjust the output of the pulsed generated field with a selected automatic therapeutic level of choice.

A micro-controller is a single integrated circuit that commonly comprises the following features: a central processing unit; serial input/output ports; data storage; clock generator or RC circuit; analog to digital converters that comprise high and low pass filters. These features of the microcontroller are necessary for the operation of the regulation and adjustment of therapeutic treatment and fail to patentably distinguish the claimed apparatus and method over the prior art of record.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Pat. No: 5211622 to Liboff et al. teach a method and apparatus including a magnetic field generator for producing a controlled, fluctuating field through cancerous tissue.

US Pat. No: 6290638 to Canedo et al. teach a method of treating seizures by subjecting a patient to time-varying magnetic fields.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON B. COLQUITT whose telephone number is (571)270-1991. The examiner can normally be reached on Monday-Friday 7:30 - 5:00 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735

/A. B. C./  
Examiner, Art Unit 3735  
12/27/2007